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| 10/541,499 | 07/07/2005 | Hisakazu Hojo | 050412 | 2008 |
| 23850 7590 05/17/2010 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. 4th Floor WASHINGTON, DC 20005 | | | | |
| EXAMINER | | | | |
| BEKKER, KELLY JO | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,499

Applicant(s)

HOJO ET AL.

Examiner

KELLY BEKKER

Art Unit

1781

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Amendments made 2/1/10 have been entered.
Claims 1-3, 5-7, and 9-12 remain pending.

Claim Rejections - 35 USC § 112 2nd Paragraph

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 112 2nd paragraph rejections of claim 5 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in light of applicant's amendments made February 1, 2010.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-7, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al. (US 6254905 B1) in view of the combination of Koumarianos (US 6488957) and Grossman (About.com, "Facts About Iron" pages 1-5 <http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html>) and Klahorst ("Calcium, An Important Nutrient" pages 1-5 http://www.ifanca.org/newsletter/2001_05.htm). The references and rejection are incorporated herein and as cited in the office action mailed September 30, 2009. Specifically regarding the newly added limitation to claims 1 and 2, the limitation is the same as that in previously presented claim 8 and thus is rejection for the same reasons of record that claim 8 was previously rejected.

Response to Arguments

Applicant's arguments filed February 1, 2010 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach the calcium ion concentration as 0-10, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion, and

wherein there is a relationship between such a calcium ion concentration and long term stability of the foods. Applicant points to examples in the specification, wherein of the calcium ion is not in the recited range the food will gel. Applicant's argument is not convincing as Hojo (Column 8 lines 34-43) teaches that the calcium ion concentration is balanced for *stability and preventing damage of the proteins and gelling of the food composition*; Hojo teaches that too little can cause instability and that too much can cause damage to the food proteins and gelling; Hojo teaches that the calcium ion concentration as about 10-500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion. Thus, as previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 the composition was stable and in order to ensure that protein destruction and gelling of the food composition was prevented. To balance a known composition based on known effects and needs would have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant's argument that there is no motivation to combine the teachings of Grossman and Hojo is

not convincing as motivation was found in some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Specifically, Hojo et al. (Hojo) teaches of a food additive composition which contains iron in the form of ferrous gluconate which is a chelating agent and calcium (Column 11 lines 4-8), however is silent to the amount of the ferrous gluconate and/or sodium iron citrate in the additive composition; Koumarios teaches that the food additive composition contains minerals, including iron and that the amount of the mineral in the food additive composition is determined based on the recommended daily dosage (Column 5 lines 8-17); Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11 mg per day and for females 8-18 mg per day (page 3); Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300 mg per day; It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate and/or sodium iron citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron desired in the final composition as taught by Koumarios; It would have been further obvious to one of ordinary skill in the art at the time the invention was made for the vitamins and minerals in the food additive, including calcium and iron, to be included in the full recommended daily amounts so that when consuming the food additive the consumers would not be required to take other additives to obtain complete daily fulfillment of the said vitamins and minerals. Thus, one would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals simultaneously; and as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate, i.e. an iron source, per 100 parts of calcium carbonate, i.e. a calcium source. Thus, the composition as taught by Hojo would comprise 0.6-1.8 parts of

ferrous gluconate and/or sodium iron citrate which are chelating agents as instantly claimed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **KELLY BEKKER** whose telephone number is **(571)272-2739**. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on **(571) 272-1401**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lien Tran/

/Kelly Bekker/

Application/Control Number: 10/541,499

Page 6

Art Unit: 1781

Primary Examiner

Art Unit 1781

Examiner

Art Unit 1781